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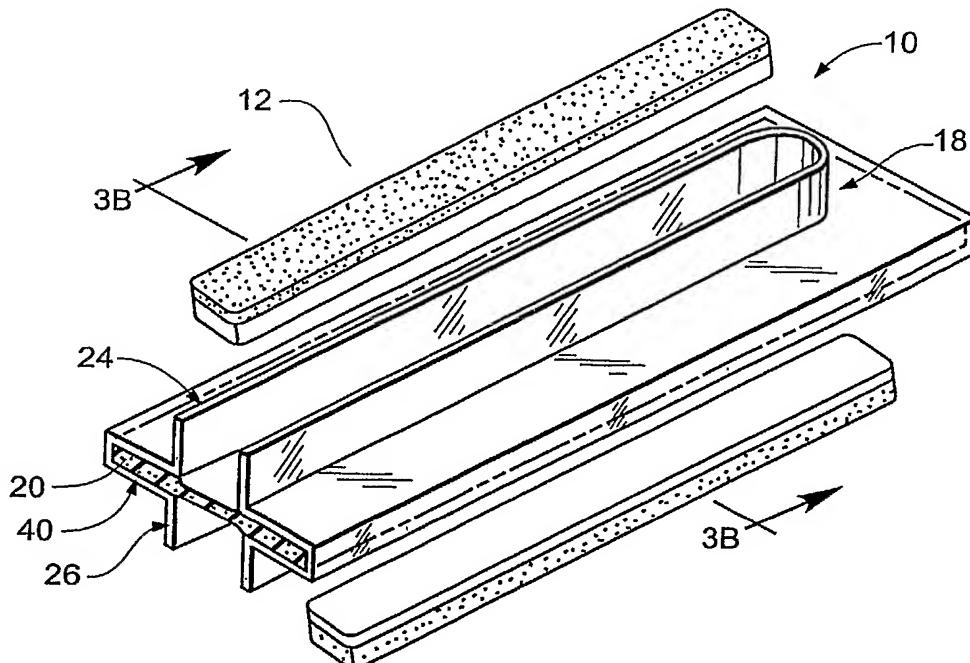
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(54) Title: SURGICAL FASTENER BUTTRESS MATERIALS



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(57) Abstract: A staple line buttress material having an adhesive surface, packaged and provided in sterile, ready-to-use form. The material can be used to retrofit surgical staplers to provide an improved staple line, and with improved ease of use.



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## SURGICAL FASTENER BUTTRESS MATERIAL

### FIELD OF THE INVENTION

5 This invention relates to surgical fastener, and to buttress materials adapted to be used in combination with such surgical fasteners.

### BACKGROUND OF THE INVENTION

10 Surgical fasteners are commonly used in surgeries to perform a variety of functions, for example to remove parts of organs (e.g., to resect tissue), to cut through organs and tissues (transection), and to create connections between structures (to create anastomoses). A variety of surgical fasteners are currently in use and include clip appliers, surgical staplers and other devices.

15 Surgical staplers are commonly used in a variety of surgical procedures including vascular, bariatric, urologic, gynecologic, thoracic and pediatric surgeries. For example, one such thoracic procedure is lung volume reduction, which resects a portion of lung to treat emphysema or other conditions. Also, one such bariatric procedure is the gastric bypass procedure, which resects a portion of the stomach to 20 create a smaller stomach to aid in weight loss.

25 Surgical staplers are also provided in many forms, including linear staplers, circular staplers, and contoured or curved staplers. Surgical staplers commonly include a pair of apposed working surfaces. In the case of a linear stapler, two apposing jaws are provided, one holding a cartridge of staples and the other being an anvil member against which the staples are to be fired. When the stapler is fired, it simultaneously emits a plurality of rows of closely spaced staples from the cartridge, and through the patient's own tissue.

In some instances, air and/or fluid leaks and/or excessive bleeding in the staple line have been reported. The term "staple line" is used herein to refer to any 30 row of stapled tissue, and the staple line can be linear, circular or curved, depending

on the type of stapler used. Leaks can occur in the cut line, and/or in the staple holes themselves. Frequently in the case of thoracic procedures, the diseased lung tissue is thin and friable and can tear at the staples as the lungs re-inflate. These air leaks can be persistent and can extend the hospital stay for a patient by weeks. As a means to  
5 alleviate these leakage problems, surgeons often reinforce the staple line by applying a buttress or plegget material to the desired stapling site, and stapling through the buttress material. The buttress material provides reinforcement to the friable tissue as it reduces the changes of tissue tearing at the staple line, and reduces staple pullout in friable tissue. The buttress material also creates a stronger staple line for increase  
10 security against air and/or fluid leaks and/or excessive bleeding both during surgery and in the crucial weeks that follow.

A variety of materials have been described for use as staple line buttress materials, including those formed of specially treated tissue (e.g., bovine pericardial tissue), alginate, polyglycolic felt, and Teflon brand materials, however only a  
15 handful have been found suitable for commercial use. These buttress materials are typically mounted in a releasable manner onto the working surfaces of a surgical stapler such that upon firing, the patient's tissue is sandwiched between the strips of buttress material.

Buttress materials are typically releasably mounted upon the working surfaces  
20 of a surgical stapler by either mechanical and/or chemical means. In some instances, an adhesive is applied to one or both surfaces of the stapler itself, or to a surface of a buttress material strip, and the strip is then applied to the corresponding working surface. For example, in the case of linear staplers, the buttress material is often attached with an adhesive to each apposing jaw. Current adhesives are typically  
25 biocompatible gels that are applied to the buttress material itself in order to hydrate the material and to create a temporary bond between the material and the stapler.

In many cases, it is generally necessary to properly align and position the  
buttress material strip onto the working surfaces of the stapler. An improperly aligned  
buttress material often results in a failed staple line. Apparatuses that include an  
30 alignment feature have been developed to aid a user in properly aligning a buttress material onto working surfaces of a stapler. For example, such an apparatus is

described in Applicant's U.S. Patent No. 5,752,965, the entire contents of which are herein incorporated by reference.

#### SUMMARY OF THE INVENTION

5       The invention provides an improved buttress material. Current methods of positioning the buttress material onto a working surface of a stapler typically involve at least two steps, a step of applying an adhesive material to the buttress material (or to the working surface of the surgical stapler) and then applying the buttress material to the working surface. The invention makes possible a one-step method of applying a  
10      buttress material to a working surface of a stapler. Also, current methods of aligning the buttress material onto a working surface of a stapler are not fail proof, even with the use of aligning devices. Often times, when a user applies an adhesive to either the buttress material or to the working surface of the stapler, too much adhesive is applied. This excess adhesive often causes the working surface to become slippery  
15      and the buttress material itself slides along the surface and becomes misaligned. Thus, the invention also provides a method of applying a buttress material to a working surface of a stapler that substantially reduces misalignments resulting from the user misapplication of the adhesive.

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#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view showing an article of buttress material according to an embodiment of the invention.

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Figure 2 is a perspective view showing the method of engagement between a surgical stapler and two articles of buttress material according to an embodiment of the invention.

Figure 3a is a partially exploded view of an aligning apparatus adapted to incorporate two articles of buttress material according to an embodiment of the invention.

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Figure 3b is a cross sectional view of the apparatus in Figure 3a taken along line 3B--3B.

Figure 4a is a perspective view illustrating the method of engagement between a surgical stapler and an aligning apparatus which incorporates two articles of buttress material according to an embodiment of the invention.

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Figure 4b is a cross sectional view of the apparatus in Figure 4a taken along line 4B--4B.

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#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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In some embodiments, the invention provides a suture line buttress material having at least one adhesive surface, the material being packaged and provided in a manner that permits the surface to be aligned with and releasably cover the working surface of a surgical fastener. The term "suture line" is used herein to refer to any row of sutured tissue. The suture line can be sutured using staples, clips and the like. Also, the suture line can be linear, circular, curved or of any other suitable pattern or design depending on the type of surgical fastener used. The buttress material is adapted for use with any surgical fastener known in the art. In preferred embodiments, the surgical fastener preferably comprises a surgical stapler, and more preferably comprises a linear stapler.

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Buttress materials are often provided in the form of a strip or other configuration where there are two major surfaces, one surface adapted to come into contact with a working surface of a surgical fastener and another surface adapted to be positioned against body tissue. The adhesive surface of the buttress material is provided on a surface that will come into contact with the working surface of the surgical fastener. The adhesive is also sufficiently tacky to permit the material, preferably without extraneous means such as removable sleeves, strings or added gels, to be retained upon the working surface of the surgical fastener in the course of the surgical fastener being positioned within the surgical site, and then to be removed from the working surface upon application of the surgical fastener.

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Buttress materials having at least one adhesive surface provide several advantages, including the ability to avoid the need for a separate step for applying an

adhesive gel. This improves the ease-of-use of loading the buttress material within the surgical fastener because currently used two-step loading processes are now converted to a one-step loading process. Furthermore, this elimination of the second step helps to reduce user misapplication of the adhesive.

5        The buttress material having at least one adhesive surface can be comprised of a single material or a composite of two or more of the same or different materials. In preferred embodiments, the buttress material includes at least one material having sufficient mechanical strength to reinforce a suture line (hereinafter "reinforcing material"). The composite of materials can be provided as a laminate of materials, a  
10      homogenous mixture of materials, a graded mixture of materials or as other suitable formations.

The reinforcing material can also be formed from synthetic or natural tissue. In certain embodiments, the reinforcing material is formed from natural animal tissue. In some cases, the natural animal tissue is a fibro-serous or serous membrane. In preferred  
15      cases, the natural animal tissue is a fibro-serous membrane comprising pericardium, preferably bovine pericardium. In some embodiments, the natural animal tissue can be a tissue of the type described in any of Applicant's own U.S. Patent Nos. 5,503,638, 5,575,803, 5,549,628, 6,468,313, 6,312,474 and 6,652,594, the entire contents of each of which are herein incorporated by reference.

20        In particularly preferred cases, the reinforcing material comprises treated bovine pericardium available from the applicant's assignee and sold under its trademark Peri-Strips Dry®. The use of this particular type of material is advantageous in that it has a much higher density of collagen than most other connective tissues and is cross linked with glutaraldehyde. The high density of the bovine pericardium  
25      provides increased structural integrity about the suture line and the cross linking with glutaraldehyde is advantageous in that it decreases the antigenicity of the tissue, thereby resulting in little or no inflammatory reaction with the adjoining body tissue. In another preferred embodiment of the invention, the reinforcing material comprises treated bovine pericardium available from the applicant's assignee and sold under its  
30      trademark Veritas®. While the preferred embodiment of the present invention employs bovine pericardium as the buttressing biomaterial, it is to be readily understood that other suitable pericardium or dura mater may be employed, including

but not limited to equine, porcupine, ovine, and human, as well as bio-compatible synthetic materials.

In a preferred embodiment of the present invention, the reinforcing material comprises a smooth, dense, nonporous membrane. A tissue of cross-linked bovine pericardium, e.g., Peri-Strips Dry® material is an example of a such a dense membrane. In other embodiments, the reinforcing material resists or substantially resists degradation *in vivo*. For example, such a reinforcing material preferably undergoes little or no hydrolysis once in contact with bodily fluid or saline solution. Cross-linked bovine pericardium, e.g., Peri-Strips Dry® material is also an example of a material which resists degradation *in vivo*. In other cases, a remodelable material is provided which is integrated into the surrounding body tissue over time. Preferably, the remodelable material comprises non-crosslinked animal tissue, for example bovine pericardium. Veritas® material is an example of a such a remodelable material.

In additional embodiments, the reinforcing material exhibits superior tensile strength, leak resistance and burst resistance. For example, the material preferably has a pre-implant tensile strength wherein the peak load is at least about 2000 grams, more preferably at least about 3000 grams and optimally at least about 4000 grams. In other cases, the material has a pre-implant tensile strength which does not significantly decrease over time once implanted *in vivo*. The pre-implant tensile strength of a material can be measured using an MTS Q45 uniaxial tensile tester. The reinforcing material also preferable has a leak pressure of at least about 90 mm Hg, more preferably at least about 150 mm Hg. In other embodiments, the reinforcing material has a burst pressure of at least about 90 mm Hg, more preferably at least about 150 mm Hg and optimally at least about 200 mm Hg. The leak pressure and burst pressure can be measured by introducing blue dye onto one side of the suture line at a constant rate and then introducing pressure. The leak pressure is the pressure at which leaking of the blue dye through the suture line is observed. The burst pressure is recorded when the pressure reaches a plateau or drops abruptly as the suture line bursts. Cross-linked bovine pericardium, e.g., Peri-Strips Dry® material is also an example of a material exhibiting superior tensile strength, leak resistance and burst resistance.

The buttress material can be provided with an adhesive surface in a variety of ways. In some embodiments, the buttress material includes a single material having

adhesive properties in its own right. The single material also preferably has sufficient mechanical strength to reinforce a suture line. For example, a hydrogel film can be provided as the single material, wherein the hydrogel is itself provided with sufficient mechanical strength. In this case, any surface of the buttress material could be

5 provided as the adhesive surface to be contacted with a working surface of a surgical fastener.

In other embodiments, an adhesive material is pre-applied upon a surface of the buttress material (which can include a single material or composite of one or more materials). In these cases, the one or more materials comprising buttress material

10 generally have reinforcing and buttressing properties rather than adhesive properties, since a separate adhesive is pre-applied to a surface. However, this is by no means required and the one or more materials can certainly include a material having adhesive properties. In this case, the surface of the buttress containing the pre-applied adhesive is provided as the adhesive surface. The adhesive material is preferably

15 formed upon a surface via a layer of film, although other configurations are also possible.

The adhesive can be pre-applied upon one or more surfaces of the buttress material according to any known methods in the art using conventional coating equipment and materials.

20 Suitable coating methods include, for instance, air knife, brush, calendar, casting, curtain, dip, extrusion, blade, knife, gravure, kiss roll, knife over blanket, knife over roll, offset gravure, reverse roll, reverse smoothing roll, rod, sprays, squeeze roll, *in vivo* polymerization, and powdered resin coating. In turn, the coated material can be in any suitable form, e.g., the form of a powdered resin composition, aqueous or solvent based

25 lattice, emulsion or dispersion.

The adhesive can be applied to one surface, two or more surfaces, or to all surfaces of the buttress material. In cases where the buttress material is porous or otherwise capable of being saturated, the adhesive can be applied to saturate the entire buttress. Preferably the hydrogel is applied to only one side, with the opposite side being

30 left uncoated, or itself treated or provided with a suitable coating or properties. The adhesive is preferably applied to one or more surfaces as a thin layer, e.g., between about

0.1 mm and about 1.0 mm in nominal thickness, and more preferably between about 0.25 mm and about 0.75 mm nominal thickness.

A variety of materials can be provided as the adhesive material. In preferred embodiments, the adhesive material comprises a biocompatible gel. In particularly preferred embodiments, the adhesive material comprises a hydrogel, which can also be described as a polymeric water-containing gel. Suitable hydrogels include those based on natural hydrogels (e.g., artificial silk, cellulosic materials) and synthetic hydrogels, such as methacrylic and acrylic esters, acrylamide hydrogels, hydrogels based on N-vinyl-2-pyrrolidone, and polyelectrolyte complexes and charged hydrogels, including blends, mixtures and copolymers thereof. The inventors have discovered that suitable hydrogels provide an optimal combination of such properties as adhesion to the buttress material of choice, adhesion to the working surfaces of a surgical fastener, flexibility, contour formation, biocompatibility, biostability, and the ability to be sterilized.

Examples of suitable hydrogels include those available under the tradename Aquatrix II™ from Hydromer, Inc., a corporation located at Branchburg, New Jersey. In a particularly preferred embodiment, the hydrogel comprises a poly(N-vinyl lactam)-chitosan gel. Such gels are described in U.S. Patent Nos. 6,379,702, 6,365,664, 6,121,375, 5,420,197, 5,258,421, and 5,156,601, the entire contents of each of which are herein incorporated by reference. Chitosan is a deacetylated chitin, and is a linear polysaccharide of deacetylated N-acetyl-D-glucosamine. Poly(N-vinyl lactam)s such as polyvinylpyrrolidone (PVP) have been used in pharmaceuticals, in certain types of films, and in some cosmetic products. They can be used to provide dermatologically-compatible gels having a hydrophilic absorbent property and K values of less than 60. Such materials are preferably stable, hydrophilic gels which comprise a blend of acid-neutralized chitosan and a poly(N-vinyl lactam), with or without a plasticizer, the poly(N-vinyl lactam) having a K value of less than about 60 and mole equivalents of acid groups of at least about 1.4.

Such preferred gels can be prepared by mixing aqueous poly(N-vinyl lactam) solution and acid neutralized chitosan in aqueous solution at a poly(N-vinyl lactam)/chitosan weight ratio of from about 12/1 to about 1/1, preferably from about 10/1 to about 5/1, to form a blend at about 5 wt. % to 40 wt. % total polymer

concentration, preferably from about 12.5 wt. % to about 25 wt. % polymer concentration, and allowing the blend to cure until a gel is formed.

In some embodiments, the adhesive surface has a predetermined adhesive strength or tack, the predetermined adhesives strength being reduced when the adhesive surface is hydrated. The terms "tack" and "adhesive strength" are used herein to describe the stickiness of the adhesive. The tack of an adhesive is typically the pull resistance (measured in dynes) exerted by the adhesive completely adhering to two surfaces being pulled apart. The higher the pull resistance, the higher the tack of the adhesive. Thus, when the adhesive material is outside of the body and in a dry form, it has sufficient tack to prevent the buttress material from being removed or realigned along the working surfaces of the surgical fastener. However, when the buttress material is placed *in vivo* where it comes into contact with tissue and body fluids, it is hydrated and this causes the surface to be easily removed from the working surfaces of the surgical fastener. Therefore, in preferred cases, the adhesive surface is packaged and provided in a manner that has sufficient tack to be securely applied to a working surface of a surgical fastener, this tack being reduced when the adhesive surface is positioned within the surgical site.

In preferred embodiments, the adhesive material of this invention can be used to deliver one or more bioactive agents, including both locally at the site of placement, or more broadly, including systemically through the patient. Such bioactive agents can serve to improve the function of the adhesive itself and/or they can serve related or unrelated functions within the body. In one embodiment, for instance, the adhesive can itself be used largely as a bioactive delivery device, with its function as a buttress material being ancillary to that. In preferred cases, one or more bioactive agents are provided that would improve healing of the stapled or otherwise sutured tissues. Examples of suitable healing bioactive agents include, but are not limited to antibiotics, anti-inflammatory agents, growth factors, and cytokines. Coagulants can also be provided to reduce the bleeding and radioactive sees can be provided to monitor the location of the buttress material within the body.

In some embodiments, the invention also provides surgical combinations, which include a buttress material according to any of the embodiments already described. For example, in some cases, a combination including a surgical fastener and at least one

article of buttress material is provided. Any surgical fastener known in the art can be used with this combination. In preferred embodiments, the surgical fastener preferably comprises a surgical stapler, and more preferably comprises a linear stapler. In other cases, a combination including an apparatus for equipping a surgical fastener with a

5       buttress material and at least one article of buttress material is provided. Suitable apparatuses for equipping a surgical fastener with a buttress material are described in U.S. Patent Nos. 5,752,965 and 6,656,193 and in U.S. Publication Nos. 20040093029, 20030120284 and 20020165563, the entire contents of each of which are herein incorporated by reference. Such apparatuses are useful for disposing one or more  
10      articles of buttress material in releasable attachment with working surfaces of a surgical fastener such that the articles are automatically lined up with those surfaces. The at least one article of buttress material can be provided as installed within a buttress material or as a separate component that is part of a surgical kit in which the buttress material is inserted within the apparatus at the surgical site.

15       In certain embodiments, the invention provides surgical methods of using the buttress material. Buttress materials of the invention can be used in a variety of surgeries, including vascular, bariatric, urologic, gynecologic, thoracic and pediatric surgeries. Common bariatric surgeries include gastric bypass and gastric banding. Gastric bypass surgeries also include the following types of surgeries: roux-en-y  
20      gastric bypass (RYGB), vertical banded gastroplasty, and biliopancreatic diversion. Common thoracic surgeries include blebectomies, bullectomies, wedge resections, segmentectomies, lobectomies, pneumonectomy, lung volume reduction surgery, and other resections of the lung and bronchus.

25       A surgical method of the invention generally includes providing one or more articles of buttress material to a working surface of a surgical fastener, positioning the surgical fastener about a section of body tissue, and applying the fastener to form a reinforced suture line. In cases where the adhesive material loses adhesive strength when hydrated *in vivo*, it is desirable to position the surgical fastener about a section of body tissue for a period of time long enough to hydrate the adhesive material so  
30      that the articles of buttress material will be easily released from the surgical fastener working surfaces.

The use of a buttress material of this invention will now be described with respect to a preferred embodiment of the invention, which is illustrated by the Figures. Figure 1 illustrates an article of buttress material 100 having a layer of adhesive material 105 pre-applied upon a surface 103 of the reinforcing material 108.

5 The adhesive material 105 comprises any suitable adhesive material and the reinforcing material 108 comprises any suitable reinforcing material. The buttress material 100 is sized and configured to be positioned and aligned upon a linear stapler jaw, with the surface 103 containing the adhesive 105 being in direct contact with the jaw surface.

10 Figure 2 illustrates a generic linear surgical stapler 46 having a staple cartridge supporting jaw 48 and an anvil supporting jaw 50 extending from a two-part handle, which in turn includes a movable part 52 and a stationary part 54 which is pivotally and removably hinged at 56 to the movable part. The cartridge supporting jaw 48 holds a cartridge body (not shown) containing a plurality of staples disposed in rows 15 oriented longitudinally to the jaw 48 in opposition to an anvil (not shown) supported by jaw 50 when the members 48 and 50 are in their closed position. Two articles of buttress material 100a and 100b are provided sized and shaped for mounting onto the working surfaces of the parts 52 and 54 of the surgical device 46. As illustrated, article 100a is positioned so that its layer of pre-applied adhesive material 105 is 20 oriented upwardly so as to adhere to the working surface of the cartridge supporting jaw 48. Likewise, article 100b is positioned so that its layer of pre-applied adhesive material 105 is oriented downwardly so as to adhere to the working surface of the anvil supporting jaw 50.

Figures 3a-3b show an apparatus 10 for equipping a surgical fastener with a 25 buttress material. The apparatus is adapted to incorporate articles of buttress material 100a and 100b in accordance with a particularly preferred embodiment. In this embodiment, the apparatus 10 is configured for use with a linear stapler.

Referring collectively to Figures 3a-3b, the apparatus 10 includes an alignment frame 18 and an internally disposed pressure equalization member 20. The 30 alignment frame 18 can be configured in any way so as to retain articles 100a and 100b of buttress material in releasable attachment within the aligning frame 18 such that the articles 100a and 100b will be automatically lined up with the apposed jaw

members of the linear stapler. In the illustrated embodiment, the aligning frame 18 includes a generally planar sheath portion 22, a first guide channel 24 and a second guide channel 26. Sheath portion 22 includes an internally disposed receiving area 40. The pressure equalization member 20 is internally disposed within the receiving area 40 and is preferably constructed from a deformable yet resilient substrate, such as foam plastic, rubber, and/or any number of suitable materials having similar properties. By providing such a uniform distribution of pressure, the pressure equalization member 20 ensures articles 100a and 100b will more readily conform to the shape and contour of the apposed working surfaces during the step of closing the surgical stapler about the apparatus 10. The resiliency of the pressure equalization member 20 is also advantageous in that it serves to releasably bias articles 100a and 100b within the receiving area 40 of the alignment frame 18.

The first guide channel 24 and the second guide channel 26 are dimensioned to regulate the engagement of the apposed working surfaces of a surgical stapler and the aligning apparatus.

Articles 100a and 100b are designed to be positioned within the receiving area 40 so as to be generally in line with the first and second guide channels 24, 26, respectively. The guide channels 24, 26 will automatically direct the apposed jaws of a surgical stapler into contact with the adhesive surface 105 of each buttress material 100a and 100b when the surgical stapler is clamped down onto the apparatus 10.

With reference now to Figures 4a and 4b, the apparatus 10 is shown fully enabled for use with a surgical stapler 46. In this embodiment, a combination including articles of buttress materials the articles 100a and 100b and an apparatus 10 for equipping a surgical fastener with a buttress material are provided. The apparatus 10 of this embodiment includes an alignment frame 18, a first article of buttress material 100a and a second article of buttress material 100b. The articles 100a and 100b are releasably disposed within the receiving area 40 so as to be generally aligned with the first and second guide channels 24, 26, respectively.

In order to equip a surgical stapler to produce reinforced staple line, the apposed working surfaces of the surgical stapler are positioned within the first and second guide channels 24, 26, respectively, and clamped down into contact with the adhesive layers 105 of the articles 100a and 100b. The surgical stapler is maintained

in this closed position for a given period of time and then pulled away from the alignment frame 18 to remove the pressure equalization means 20, along with the articles of buttress material 100a and 100b from within the receiving area 40. The adhesive layer 105 forms a sufficient bond between articles 100a and 100b and the  
5 apposed working surfaces of the surgical stapler such that, when the surgical stapler is opened from the previously clamped position, the articles 100a and 100b remain releasably attached to the apposed working surfaces of the surgical stapler and the pressure equalization member 20 may be removed from between the articles 100a and 100b. The surgical stapler is then fully equipped with articles 100a and 100b such that  
10 the apposed working surfaces thereof may be positioned about a section of body tissue to form a reinforced staple line in accordance with the present invention.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended  
15 claims.

## WHAT IS CLAIMED IS:

1. A surgical fastener buttress material having an adhesive surface, the material being packaged and provided in a manner that permits the adhesive surface 5 to be aligned with and releasably cover a working surface of a surgical fastener.
2. The material according to claim 1 wherein the buttress material is packaged and provided in a manner that permits the adhesive surface to be aligned with and releasably cover a working surface of a surgical fastener in a one step loading process.
3. The material according to claim 1 wherein the adhesive surface has an adhesive strength sufficient to permit the material, without extraneous means, to be retained upon the working surface of the surgical fastener in the course of the surgical fastener being positioned within the surgical site, and to then be removed from the working surface upon application of the surgical fastener.
4. The material according to claim 1 wherein the adhesive surface has a predetermined adhesive strength when retained upon the working surface of a surgical fastener, the adhesive strength being reduced when the adhesive surface is positioned and hydrated *in vivo*.
5. The material according to claim 1 wherein the adhesive surface is a 20 surface comprising a pre-applied adhesive material.
6. The material according to claim 6 wherein the pre-applied adhesive material comprises a pre-applied hydrogel.
7. The material according to claim 6 wherein the pre-applied adhesive material further includes one or more bioactive agents.
8. The material according to claim 1 wherein the buttress material 25 includes at least one reinforcing material having sufficient mechanical strength to reinforce a surgical fastener suture line.
9. The material according to claim 8 wherein the buttress material includes a composite of two or more materials, with at least one of the materials being 30 a reinforcing material.
10. The material according to claim 8 wherein the at least one reinforcing material substantially resists degradation when implanted *in vivo*.

11. The material according to claim 8 wherein the at least one reinforcing material has a pre-implant tensile strength having a peak load of at least about 2000 grams.

12. The material according to claim 8 wherein the at least one reinforcing material

5 has a pre-implant tensile strength which does not significantly decrease over time when implanted *in vivo*.

13. The material according to claim 8 wherein the at least one reinforcing material

10 has a leak pressure or burst pressure of at least about 90 mm Hg.

14. The material according to claim 8 wherein the at least one reinforcing material comprises a natural animal tissue.

15. The material according to claim 14 wherein the natural animal tissue comprises a fibro-serous or serous membrane.

16. The material according to claim 15 wherein the natural animal tissue comprises a fibro-serous membrane comprising bovine pericardium.

17. The material according to claim 8 wherein the at least one reinforcing material also has an adhesive strength sufficient to permit the material, without extraneous means, to be retained upon the working surface of the surgical fastener in 20 the course of the surgical fastener being positioned within the surgical site, and to then be removed from the working surface upon application of the surgical fastener.

18. A combination comprising a surgical fastener having at least one working surface and a buttress material according to claim 1 positioned on the at least one working surface.

25 19. The combination of claim 18 wherein the surgical fastener comprises a surgical stapler.

20. An apparatus for facilitating alignment and application of a buttress material to a working surface of a surgical fastener, the device incorporating a buttress material according to claim 1.

30 21. The apparatus according to claim 20 further comprising an aligning frame which retains one or more articles of the buttress material in releasable

attachment with the aligning frame such that the one or more articles will be automatically lined up with apposed working surfaces of a surgical fastener.

22. A surgical kit for facilitating application of an article of buttress material to the apposed working surfaces of a surgical fastener, the kit including one or more articles of buttress material according to claim 1 and an aligning apparatus.

23. The surgical kit according to claim 22 wherein the one or more articles of buttress material are adapted to be loaded into the aligning apparatus.

24. A surgical method comprising the steps of:  
providing one or more articles of buttress material according to claim 1;  
applying the one or more articles of buttress material to a working surface of a surgical fastener;  
positioning the surgical fastener about a section of body tissue; and  
applying the fastener to form a reinforced suture line.

25. The surgical method of claim 24 wherein the step of positioning the surgical fastener comprises positioning the surgical fastener about a section of body tissue for a period of time long enough to hydrate the adhesive surface.

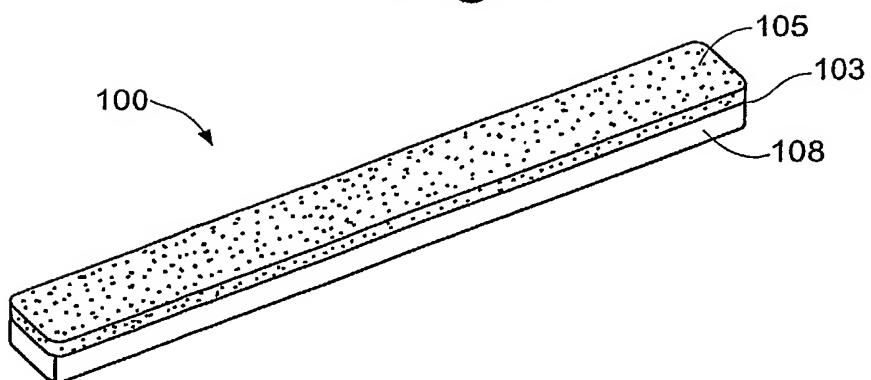
26. The surgical method of claim 24 wherein the step of applying the fastener comprises applying the fastener once the adhesive surface has been hydrated.

27. The surgical method of claim 24 wherein the method is adapted for use in a surgical procedure selected from the group consisting of vascular, bariatric, urologic, gynecologic, thoracic and pediatric surgeries.

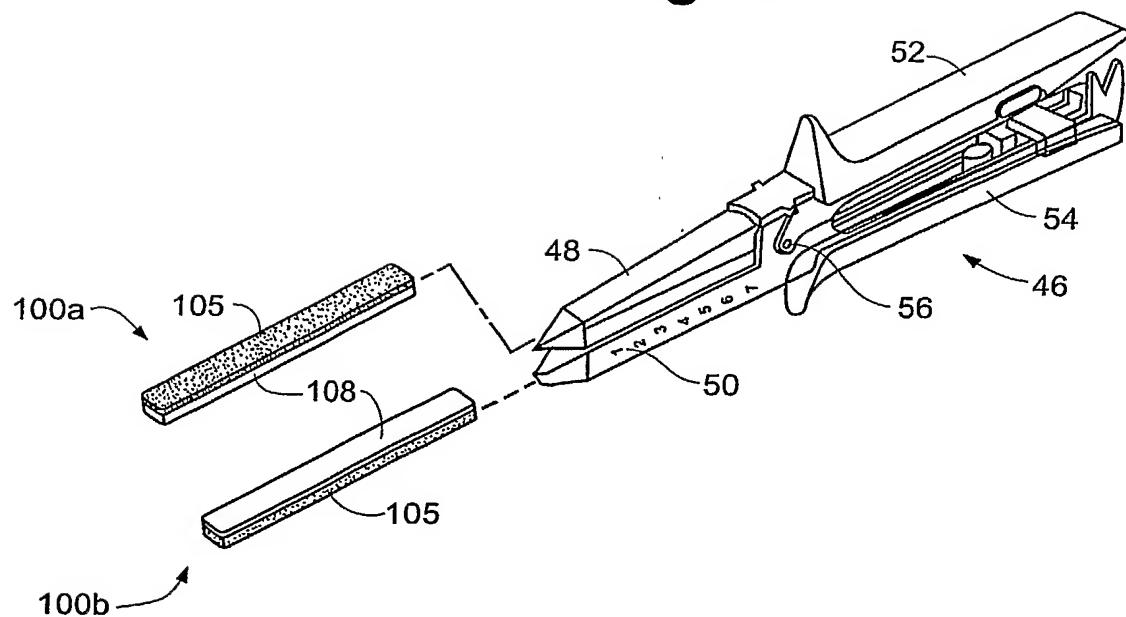
28. The surgical method of claim 27 wherein the method is adapted for use in a bariatric surgical procedure selected from the group consisting of roux-en-y gastric bypass, vertical banded gastroplasty, and biliopancreatic diversion.

29. The surgical method of claim 27 wherein the method is adapted for use in a thoracic surgical procedures selected from the group consisting of blebectomies, bullectomies, wedge resections, segmentectomies, lobectomies, pneumonectomy, lung volume reduction surgery, and other resections of the lung and bronchus.

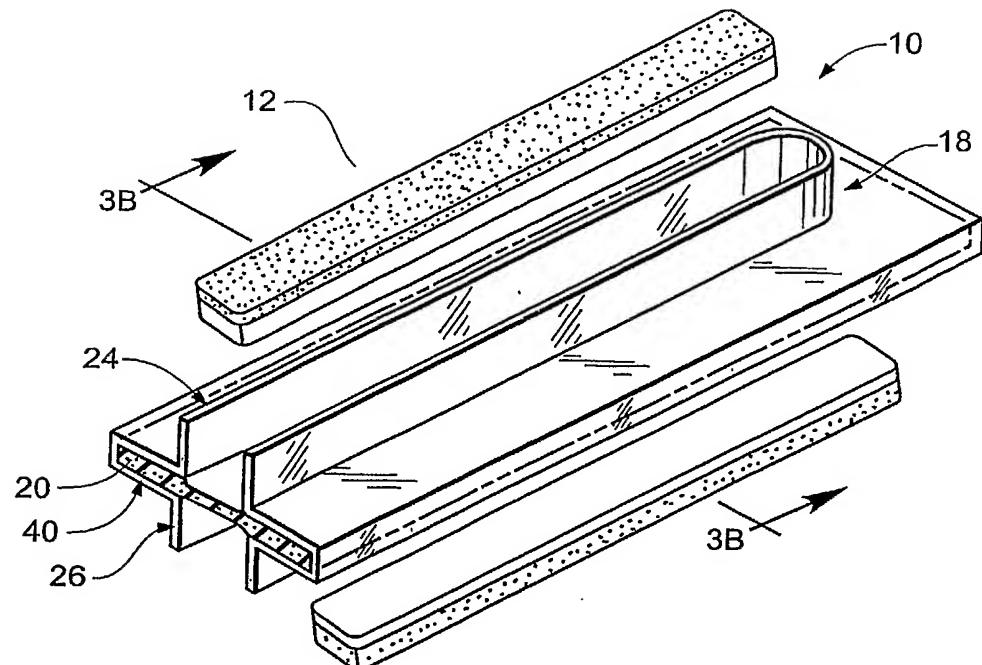
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***Fig. 1***

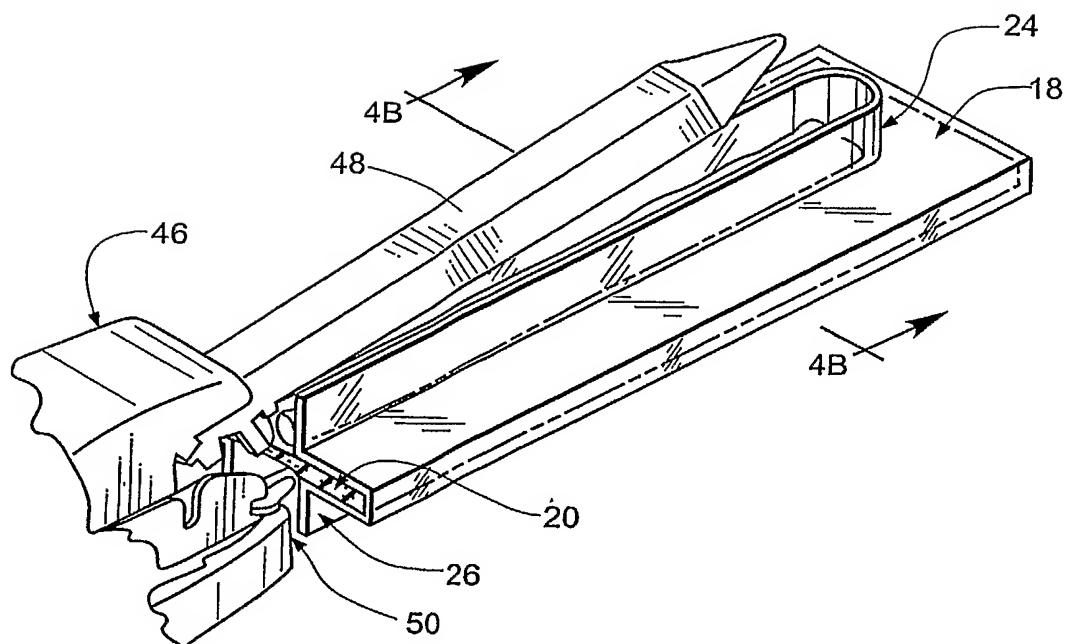
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***Fig. 2***

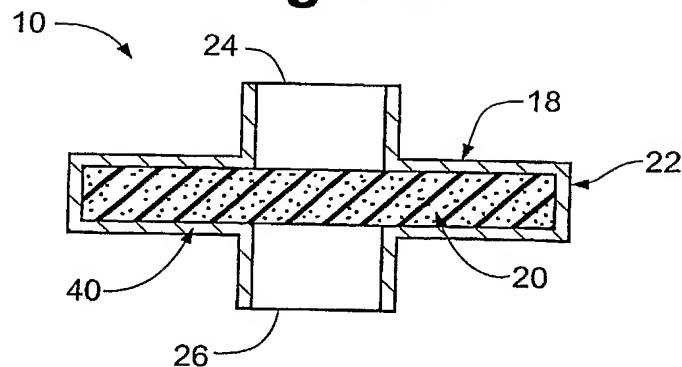
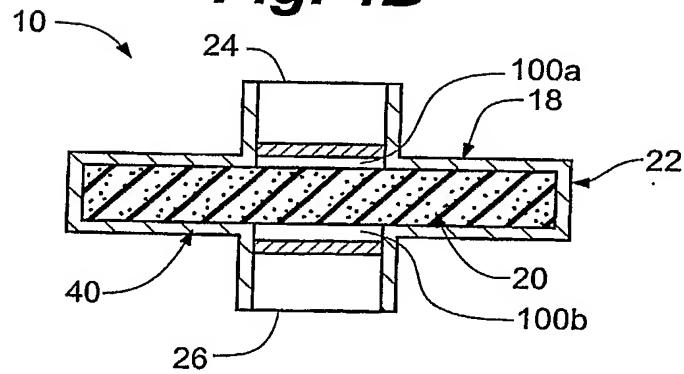
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*Fig. 3A*

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*Fig. 4A*

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***Fig. 3B******Fig. 4B***

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/003121

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. A61B17/072

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 752 965 A (FRANCIS ET AL.) 19 May 1998 (1998-05-19) cited in the application abstract; figures column 7, line 66 - column 9, line 20 column 11, line 60 - column 12, line 11 column 15, lines 2-11 column 16, line 49 - column 17, line 2 -----	1-3,5, 8-23
X	US 2004/093029 A1 (ZUBIK ET AL.) 13 May 2004 (2004-05-13) abstract; figures paragraph [0049]	1-3,5,6, 8-19
Y	----- -----	4,7

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

11 May 2006

Date of mailing of the international search report

18/05/2006

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## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/003121

## C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 379 702 B1 (LORENZ DONALD H ET AL) 30 April 2002 (2002-04-30) cited in the application column 6, lines 34-62 -----	4,7
X	US 2003/120284 A1 (PALACIOS ET AL.) 26 June 2003 (2003-06-26) cited in the application abstract; figures paragraphs [0046] - [0050], [0106], [0107] -----	1-3,5, 8-19
A	US 2002/165559 A1 (GRANT ET AL.) 7 November 2002 (2002-11-07) paragraphs [0038], [0039]; figures 1-4 -----	1,3, 17-23

**INTERNATIONAL SEARCH REPORT**International application No.  
PCT/US2006/003121**Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 24–29 because they relate to subject matter not required to be searched by this Authority, namely:  
**Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery**
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No PCT/US2006/003121	
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